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09/936,534	02/03/2003	Catia Bastioli	13929/T/B/A	7100
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Byran Cave LLP 1290 Avenue of the Americas 33rd Floor New York, NY 10104			SAYALA, CHIHAYA D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/936,534	BASTIOLI ET AL.
	Examiner C. SAYALA	Art Unit 1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

1) Responsive to communication(s) filed on 3/9/2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,7,11-13 and 16-22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,7,11-13 and 16-22 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08c)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 12 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, line 2, "and " in the phrase 'inulin and the mixtures" lacks proper antecedent basis since in claim 1, it is 'inulin **or** mixtures".

Also in claim 12, line 2, "and/or" should be "**and**" alone.

In claim 11, line 2, "and/or" lacks proper antecedent basis and should be changed to "**and**".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 102

2. Claims 1, 7, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/30691.

Examples 2 and 3 show inulin and potato starch that are kneaded and at page 2 of the patent, the patent teaches that the compositions can be kneaded or alternatively, extruded with glycerol at the same temperatures (also page 2). The reference therefore, meets the composition. Note that the reference product is chewable or "that can be chewed". The terminology "for animals" is use limitation that does not add

patentability to an old and known composition/product. This claim reads on inulin only and it is inherent that the product can be chewed.

3. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0111663.

EP '663 discloses a tubular product made from inulin and thermoplastic polymer. See claims 5 & 8.

Note that the reference product is chewable or "that can be chewed". The terminology "for animals" is use limitation that does not add patentability to an old and known composition/product. This claim reads on inulin only.

4. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/09176.

The patent discloses inulin that is polymerized with thermoplastic polymers.

5. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Havernen et al. (US Patent 6313203).

The patent discloses Inulin with thermoplastic polymers. See col. 2, line 62, line 67 and col. 3, lines 20-30.

6. Claims 12 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/30691.

Claim 12 is in a product-by-process format. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. " *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Nonetheless, the ingredients are all disclosed by Example 2, as discussed above. The temperature is the same. The ingredients are extruded.

With regard to claim 22, the recitation is to the production of one of the ingredients and is therefore, in a product-by-process format. The patentability of a product does not depend on its method of production and neither does it depend on the production of one of the ingredients.

7. Claims 12 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0111663.

Claim 12 claims a mixture of inulin with thermoplastic polymers, written in a product-by-process format. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the

product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. " In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985).

See the claims in the EP patent. Claim 1 which shows a tubular membrane prepared as in claim 12 which is pertinent to the extent of its disclosure of the mixture claimed herein, i.e. polymer and inulin, capable of being extruded.

With regard to claim 22, the recitation is to the production of one of the ingredients and is therefore, in a product-by-process format. The patentability of a product does not depend on its method of production and neither does it depend on the production of one of the ingredients.

8. Claims 12 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 93/09176.

See claims 1-5. Claim 1 describes a polysaccharide given as inulin in claim 5, which contains a moiety which will undergo polymerization. Therefore, the material is a combination of inulin and a polymer and is "thermochemically processable". Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

With regard to claim 22, the recitation is to the production of one of the ingredients and is therefore, in a product-by-process format. The patentability of a product does not depend on its method of production and neither does it depend on the production of one of the ingredients.

9. Claims 12 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Guttag (US Patent 5346929).

See claims 1 and 11 that recite inulin with polymers. Since inulin is the same, then it is inherently "thermoplastically processable".

Claim 1 recites a synthetic polymer and a natural polymer, which claim 11 recites is an inulin; synthetic polymers are described at col. 4, lines 10-16. The claim requires two elements, inulin and thermoplastic polymers. See col. 2, line 34.

Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

10. Claim 12 and 22 are rejected under 35 U.S.C. 102(e) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Van Havernen et al. (US Patent 6313203).

The claims show a mixture of a thermoplastic polymer with inulin. See claim 4.

See col. 2, lines 10-11 that describe inulin as being the polyfructose (claim 1), which is a known fact in basic chemistry. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976).

Claim Rejections - 35 USC § 103

11. Claims 1, 7, 11-13, 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leo (US Patent 5419283) and Wang (US Patent 5922379) in view of Anantharaman et al. (US Patent 5952033) and further in view of Van Haveren et al. (US Patent 6313203) and Bengs et al. (US Patent 6406530) and optionally, with Licari (US Patent 6455068).

Both Leo and Wang teach biodegradable thermoplastic products.

Leo discloses a chew toy for pets make from a plastic material. At col. 1, lines 27+ pantentee states:

The preferred materials are thermoplastic blends obtained by processing starch and said thermoplastic polymers in the presence of a limited amount of water (10-40% wt. referred to the starch/water system) or of a polyol plasticizer (10-40% wt. referred to the starch/polyol system), under extrusion cooking conditions thereby to provide a melt to be extruded and transformed into pellets for use in injection moulding or to be directly injection moulded.

At col 1, line 33-40 states that the materials thermoplastic blends of starch and thermoplastic polymers in the presence of water and polyols as plasticizers, can be extruded.

Wang teaches a biodegradable protein/starch based thermoplastic composition that can be extruded and consumed by animals and. See col 8, lines 13-14, col 2, line 17. Plasticizers are shown at col 4 line 46+. The amount of starch is 20-60% (col 3, lines 63-64).

Both patents do not teach inulin. However, inulin, a polysaccharide/starch, is known to be a stabilizer for extrudable thermoplastics. See Van Haveren et al (col 2, line 62-64 and abstract). Bengs et al. teach a mixture of starches including inulin, used in biodegradable thermoplastic materials that can be thermoplastically processable using techniques such as injection holding or extrusion. Col 1, line 32, col 2, lines 58, col 3, lines 20-21, col 4 line 66-67, col 5, lines 21-28. Note that the *mixture* of starches is given to be in an amount 33-90%.

Ananthararman et al teach the use of inulin in pet food products is beneficial in an amount of at least 0.25%. See col 1, which states that inulin promotes bifido- and lacto-bacteria in the GI tract at the expense of pathogens and is very beneficial for animals and inulin has been used as a vet diet for pets. Col 1, 50-52. col 2, lines 7-12. This patent establishes that inulin has been used for pet foods and that "for pet foods, their use has been confined to specialty veterinary products such as the Eukanuba product and to pet treats. Similarly, for human foods, their use has been confined to specialty products." (Col. 2, lines 7-10).

Therefore, while Leo and Wang establish biodegradable, thermoplastically processable starch containing products have been used for pet chews (in the form of bones), Anantharaman et al., by establishing that inulin provides benefits for the GI tract for pets, and that inulin has been used for pet treats, motivates one of ordinary skill in the art to incorporate inulin in biodegradable, thermoplastically processable products of Leo and Wang in pet products with plasticizers or glycerol, etc. In fact the patents to Bengs et al. and Van Haveren et al. show shaped, extrudable, biodegradable, inulin containing articles wherein inulin additionally acts as a stabilizer for such a thermoplastically processable compositions (Van Haveren et al.). Patents to Anantharaman et al. and Van Haveren et al. show inulin amounts of "at least 0.25%" and mixtures of starch including inulin between 33% to 90%, and to determine amounts for various pet chew articles would have been obvious based on such disclosure. With regard to claim 13, Leo shows a bone. With regard to claim 12, the Anantharaman et al. patent shows the extrusion temperature at col 4, line 10-15.

Summarizing:

- Leo teaches the use of thermoplastic blends of starch and polymers and polyols as plasticizers, extruded to a chew toy.
- Wang et al. teach biodegradable protein/starch thermoplastic compositions that can be extruded and consumed by animals.
- Anantharaman et al. teach the usefulness of inulin in pet foods and disclose that it has been used as a vet diet for pets.

- Van Haveren et al. disclose that inulin is a stabilizer for extrudable thermoplastics.
- Bengs et al. teach a mixture of starches including inulin, in a composition that is thermoplastically processable using extrusion techniques and injection molding.

With regard to claim 22, Licari teaches that such a feature was already known in the art at the time the invention was made and applicant was not the first to invent the preparation of oligofructans. Note that claim 22 is a process step, in a product/composition claim and has little relevance to the patentability of the claim, particularly when the process step is to the preparation of *one* of the elements of the composition claim.

Response to Arguments

Applicant's arguments filed 3/9/2009 have been fully considered but they are not persuasive.

Applicant has presented claim 12 in a product-by-process format. MPEP 2113 states as follows:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garner*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

There is no evidence that the process steps by which the product is made are unique or that the product can only be defined by the process steps. In fact, prior art shows the process to be old and known. Therefore, the product is also known by prior art.

Regarding the WO '691 patent, applicant has urged that the examiner has erred in detailing what Example 2 shows and this be the basis for allowance of all the claims. However, the patent teaches kneading to be alternative to extrusion.

The remaining discussions of claim 14, now cancelled, are not being addressed here.

With regard to the rejection under 35 USC 103, applicant urges that with respect to the Leo patent , the examiner does not assert anywhere in the action that inulin teaches inulin as a polysaccharide and inulin is substitutable as a starch, since the Examiner has acknowledged that inulin is a polysaccharide. Section 103 requires us to presume full knowledge by the inventor of the prior art in the field of his endeavor. *In re Winslow*, 151 USPQ 48 (CCPA 1966). In any event, while it is well known in the art that inulin is a starch, this knowledge is being made of record for applicant's convenience. The argument in relation to the degree of polymerization of inulin being between 2 and 60 and the low molecular mass of starch, it is not clear how this argument establishes the patentability of these product claims. Furthermore, that "starch" has a low molecular mass must be clarified. It is not clear if all starches have a low molecular mass. It is also not clear when the patents applied above show starch being polymerized with inulin, whether applicant is implying that these polymers are not as disclosed by these

patents. Furthermore, inulin is known as a starch and therefore, this argument does not clearly establish patentability.

The remaining arguments either state that one reference or the other does not mention inulin either as a polysaccharide or as a starch. The evidence of record should explain this well enough. Therefore, such arguments cannot establish patentability.

With regard to motivation and to Wang (or Leo) not providing such for making the combination, the Office action summarizes each of the references and points out its relevance. To repeat, Wang teaches a biodegradable protein/starch extruded chew and Van Haveren teaches that inulin acts as a stabilizer for extrudable thermoplastics. This alone would have provided the motivation. Applicant is urged to review the action itself. Further, Anantharaman teaches the usefulness of FOS in pet foods providing many benefits. As for perfecting priority, applicant is reminded that the WO patents available as family patents to the US patents used herein, would be applicable when such priority is perfected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala, whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/C. SAYALA/
Primary Examiner, Art Unit 1794**

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